

APPENDIX B
CLEAN VERSION OF ALL PENDING CLAIMS (UNOFFICIAL)

26. A solvent vehicle, capable of solubilizing a drug with low aqueous solubility, prepared by a process comprising;

- a) dissolving a drug with low aqueous solubility in a pharmaceutically acceptable dipolar aprotic solvent and/or acid;
- b) further dissolving the composition of step a) in a pharmaceutically acceptable aqueous secondary solvent; and
- c) removing the dipolar aprotic solvent and/or acid from the composition of step b).

27. The solvent vehicle of claim 26, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.

28. The solvent vehicle of claim 27, wherein said aprotic solvent comprises N,N-dimethylacetamide.

29. The solvent vehicle of claim 27, wherein said aprotic solvent comprises castor oil.

30. The solvent vehicle of claim 27, wherein said aprotic solvent comprises dimethylsulfoxide.

31. The solvent vehicle of claim 27, wherein said aprotic solvent comprises 1,2,-propylene-diol.

32. The solvent vehicle of claim 27, wherein said aprotic solvent comprises glycerol.

33. The solvent vehicle of claim 27, wherein said aprotic solvent comprises polyethylene glycol-400.

34. The composition of claim 26, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.
35. The solvent vehicle of claim 34, wherein said secondary solvent comprises an aqueous lipid emulsion.
36. The solvent vehicle of claim 35, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.
37. The solvent vehicle of claim 35, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.
38. The solvent vehicle of claim 37, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.
39. The solvent vehicle of claim 35, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.
40. The solvent vehicle of claim 39, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.
41. The solvent vehicle of claim 34, wherein said secondary solvent comprises water.
42. The solvent vehicle of claim 34, wherein said secondary solvent comprises saline solution.
43. The solvent vehicle of claim 34, wherein said secondary solvent comprises dextrose solution.
44. The solvent vehicle of claim 43, wherein said dextrose solution comprises 5% to 70% dextrose in water.

45. The solvent vehicle of claim 44, wherein said dextrose solution comprises 5% or 10% dextrose solution.

46. The solvent vehicle of claim 34, wherein said secondary solvent comprises glacial acetic acid.

47. The solvent vehicle of claim 26, wherein said secondary solvent comprises a lipid solution.

48. The solvent vehicle of claim 26, wherein said secondary solvent comprises a parenteral infusion fluid.

50. The solvent vehicle of claim 26, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.

51. The solvent vehicle of claim 26, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.

52. The solvent vehicle of claim 26, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and aqueous lipid.

53. The solvent vehicle of claim 52, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

54. The solvent vehicle of claim 53, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.

55. The solvent vehicle of claim 53, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

56. The solvent vehicle of claim 53, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.

57. The solvent vehicle of claim 26, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.

58. The solvent vehicle of claim 26, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.

59. The solvent vehicle of claim 58, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.

60. The solvent vehicle of claim 26, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

61. The solvent vehicle of claim 26, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

62. The solvent vehicle of claim 61, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.

63. The solvent vehicle of claim 26, wherein said composition is administered to an animal.

64. The solvent vehicle of claim 26, wherein said composition is administered to a human.
65. The solvent vehicle of claim 26, wherein said composition is administered by parenteral injection.
66. The method of claim 65, wherein said parenteral injection is intravascular or intravenous injection.
67. The solvent vehicle of claim 26, wherein said composition is administered as an aerosol.
68. The solvent vehicle of claim 26, wherein said vehicle is lyophilized.
69. The solvent vehicle of claim 26, where the acid is acetic acid.
70. The solvent vehicle of claim 26, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.
71. The solvent vehicle of claim 26, where removing the dipolar aprotic solvent and/or acid comprises lyophilization.
72. The solvent vehicle of claim 26, wherein the process further comprises reconstituting the composition of step c) in a pharmaceutically acceptable aqueous solution.
73. The solvent vehicle of claim 72, wherein said pharmaceutically acceptable aqueous solution comprises water, saline solution, dextrose solution, aqueous lipid emulsion, glacial acetic acid, or lipid solution.
74. The solvent vehicle of claim 73, wherein said pharmaceutically acceptable aqueous solution comprises water.

75. The solvent vehicle of claim 73, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.

76. The solvent vehicle of claim 73, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.

77. The solvent vehicle of claim 76, wherein said dextrose solution comprises 5% to 70% dextrose in water.

78. The solvent vehicle of claim 76, wherein said dextrose solution comprises 5% or 10% dextrose solution.

79. The solvent vehicle of claim 73, wherein said secondary solvent comprises a parenteral infusion fluid.

80. The solvent vehicle of claim 26, wherein the drug with low aqueous solubility is pimaricin.

81. A method for preparing a solvent vehicle comprising:

- a) obtaining a pharmaceutically acceptable dipolar aprotic solvent and/or acid;
- b) dissolving a drug with low aqueous solubility in said dipolar aprotic solvent and/or acid;
- c) further dissolving composition of step b) in a pharmaceutically acceptable aqueous secondary solvent; and
- d) removing the dipolar aprotic solvent and/or acid from the composition of step c).

82. The method of claim 81, where the acid is acetic acid.

83. The method of claim 81, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.

84. The method of claim 81, where removing the dipolar aprotic solvent and/or acid is by lyophilization.

85. The method of claim 81, further comprising reconstituting the composition of step d) by the addition of a pharmaceutically acceptable aqueous solvent.

86. The solvent vehicle of claim 85, wherein said pharmaceutically acceptable aqueous solution comprises water, saline solution, dextrose solution, aqueous lipid emulsion, glacial acetic acid, or lipid solution.

87. The method of claim 81, where the drug is pimaricin.